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10/726,261	12/01/2003	Sung Hoi Choi	61812-00003	3353

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EXAMINER	
RUTHKOSKY, MARK	

ART UNIT	PAPER NUMBER
1795	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/726,261	**Applicant(s)** CHOI, SUNG HOI	
	Examiner Mark Ruthkosky	**Art Unit** 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _06 March 2008_.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1-37,48 and 49_ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _1-37,48 and 49_ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/6/2008 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-17, 18-37 and 48-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller (US 6,294,281), in view of Sobolewski (US 6,689,439), and further in view of Imazato (US 6,869,721.)

The instant claims are to an electrochemical cell for generating electrical energy from oxidation-reduction electron transfer, said electrochemical cell for use with active implantable medical devices, and said electrochemical cell comprising an anode having a first immobilized enzyme deposited on a first surface of said anode, said first immobile enzyme capable of catalyzing an electrooxidation of a reducing agent; a cathode having a second immobilized

enzyme deposited on a second surface of said cathode, said second enzyme capable of catalyzing an electroreduction of an oxidizing agent, an aqueous solution containing said reducing agent and said oxidizing agent, said solution in contact with said first immobilized enzyme and said second immobilized enzyme; and a housing for providing mechanical support and electrical separation of said anode and said cathode, wherein the anode or cathode comprises a nanostructured material.

Heller (US 6,294,281) teaches an electrochemical cell for generating electrical energy from oxidation-reduction electron transfer, said electrochemical cell for use with active implantable medical devices, and said electrochemical cell comprising an anode having a first immobilized enzyme deposited on a first surface of said anode, said first immobile enzyme for catalyzing an electrooxidation of a reducing agent; a cathode having a second immobilized enzyme deposited on a second surface of said cathode, said second enzyme for catalyzing an electroreduction of an oxidizing agent, an aqueous solution containing said reducing agent and said oxidizing agent, said solution in contact with said first immobilized enzyme and said second immobilized enzyme; and a housing for providing mechanical support and electrical separation of said anode and said cathode (see at least claims 1-29 and figures 1-5.) The electrochemical enzymes include glucose oxidase and lacasse immobilized on a substrate (see col. 3, lines 15-20, col. 4, lines 12-end, col. 5, lines 30-50, col. 12, lines 30-55; and col. 14, lines 35-60.) The substrate may include carbon, graphite, gold, platinum and titanium material in various shapes including rods (see col. 4, lines 12-end; col. 10, lines 25-40.) The electrodes may include an enzyme with a substrate in the form of a sol gel, which is a biocolloidal material (col. 12, lines 30-55.) The housing includes a permeable membrane for preventing macromolecules from

entering the cell (see figures 3-5 and cols. 4 and 14.) Heller does not teach that the anode or cathode comprises a nanostructured material or that the substrate comprises a plurality of nanostructured rods or wires. As noted, Heller teaches a substrate including carbon, graphite, gold, platinum and titanium material in various shapes including rods (see col. 4, lines 12-end; col. 10, lines 25-40.)

Sobolewski (US 6,689,439) teaches an electrochemical cell for generating electrical energy from oxidation-reduction electron transfer, said electrochemical cell including electrode substrates that include vertically formed, nanostructured rods and wires (see claims 1-26, figs. 1-4.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a substrate that comprises a plurality of nanostructured rods or wires as taught by Sobolewski in order to improve conductivity in the electrode and provide appropriate gas diffusion and mechanical strength for a fuel cell electrode (see '439, col. 2, lines 45-65; col. 3, lines 45-55.)

Imazato (US 6,869,721) teaches an electrochemical cell for generating electrical energy from oxidation-reduction electron transfer, said electrochemical cell including electrode substrates that include nanostructured rods and wires (see claims 1-16, col. 4.) The rods may further comprise gold and titanium (see col. 3, lines 25-45.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a substrate that comprises a plurality of nanostructured rods or wires as taught by Imazato in order to improve conductivity in the electrode (see '721, col. 3, lines 35-40) and provide appropriate gas diffusion and mechanical strength for a fuel cell electrode (col. 4, lines 10-20.)

With regard to claim 49, the references do not teach an electrochemical cell wherein the electrochemical cell has a total power of about 1000 μW to about 10,000 μW. This is an inherent feature of the fuel cell based upon the amount of material used in the cell. As the materials are the same, one of ordinary skill in the art would have the knowledge to use the proper amount of material in order to achieve the desired amount of power from the fuel cell. The artesian would have found the claimed invention to be obvious in light of the teachings of the references.

Response to Arguments

Applicant's arguments filed 1/28/2008 have been fully considered but they are not persuasive.

With regard to the rejection under 35 U.S.C. 103(a) as being unpatentable over Heller (US 6,294,281), in view of Sobolewski (US 6,689,439), and further in view of Imazato (US 6,869,721), applicant argues that Sobolewski and Imazato are drawn to entirely different cells. Applicant argues that Sobolewski and Imazato are drawn to gas fuel cells based on burning gas in the presence of oxygen to generate electricity. Applicant further argues, "**A person of ordinary skill in the art would recognize that the catalyst and substrate in an electrochemical cell and the same words in a gas fuel cell have entirely different meanings, and thus the advantages taught by Sobolewski and Imazato are entirely irrelevant to Heller**."

These arguments are not persuasive for the following reasons:

First, Applicant has erred in their description of the prior art. Sobolewski and Imazato are not drawn to gas fuel cells based on *burning gas in the presence of oxygen* to generate electricity. The fuel cells are electrochemical cells that generate electrical energy from oxidation-reduction electron transfer, wherein a fuel such as hydrogen is catalyzed at the anode of the fuel cell to form hydrogen ions and electrons. The electrons are used to power a device. The electrons then flow to the cathode, where they react with catalyzed oxygen and the hydrogen ions to form water. It is noted that all three of the prior art inventions are fuel cells.

Heller (US 6,294,281) teaches a biological fuel cell for generating electrical energy from an equivalent oxidation-reduction electron transfer reaction. The fuel cell is used with active implantable medical devices, and comprises the following features disclosed in applicant's invention: an anode having a first immobilized enzyme deposited on a first surface of said anode, said first immobile enzyme for catalyzing an electrooxidation of a reducing agent; a cathode having a second immobilized enzyme deposited on a second surface of said cathode, said second enzyme for catalyzing an electroreduction of an oxidizing agent, an aqueous solution containing said reducing agent and said oxidizing agent, said solution in contact with said first immobilized enzyme and said second immobilized enzyme; and a housing for providing mechanical support and electrical separation of said anode and said cathode (see at least claims 1-29 and figures 1-5.) The electrochemical enzymes include glucose oxidase and lacasse immobilized on a substrate (see col. 3, lines 15-20, col. 4, lines 12-end, col. 5, lines 30-50, col. 12, lines 30-55; and col. 14, lines 35-60.) The substrate may include carbon, graphite, gold, platinum and titanium material in various shapes including rods (see col. 4, lines 12-end; col. 10, lines 25-40.) The electrodes may include an enzyme with a substrate in the form of a sol gel,

which is a biocolloidal material (col. 12, lines 30-55.) The housing includes a permeable membrane for preventing macromolecules from entering the cell (see figures 3-5 and cols. 4 and 14.)

The claimed feature that Heller does not teach is that the anode or cathode substrate comprises a nanostructured material or a plurality of nanostructured rods or wires. As all three fuel cells use a catalytic electrode that includes a catalyst and a substrate, one skilled in the art would recognize that the catalysts taught by the prior art may be used on such substrates in order to hold the catalyst material and transfer electrons from or to the electrode. Catalysts and substrates are essential for fuel cell reactivity and are well defined in the prior art. Sobolewski (US 6,689,439) teaches an electrochemical cell including electrode substrates that include vertically formed, nanostructured rods and wires (see claims 1-26, figs. 1-4) that improve conductivity in the electrode and provide appropriate gas diffusion and mechanical strength for a fuel cell electrode (see ‘439, col. 2, lines 45-65; col. 3, lines 45-55.) Imazato (US 6,869,721) teaches an electrochemical cell including electrode substrates that include nanostructured rods and wires that may further comprise gold and titanium that improve conductivity in the electrode (see ‘721, col. 3, lines 35-40) and provide appropriate gas diffusion and mechanical strength for a fuel cell electrode (col. 4, lines 10-20.) Thus, one skilled in the art would appreciate these features taught in the reference applied.

Applicant further argues that the advantages noted by the Examiner, such as improved conductivity in the electrode, good gas diffusion and improved mechanical strength as motivation to combine the references is irrelevant with regard to the cell of Heller because the fuel cell of Heller <u>does not</u> use gas and improved mechanical strength of a particular component

is of no concern since the electrochemical cell in Heller is for use in an implantable device where mechanical impact on the cell is not a concern whatsoever.

This argument is also not persuasive or accurate. The Heller reference teaches using gaseous oxygen as the oxidant of the cathode (col. 13, line 30), thus Heller <u>does</u> use gas and diffusion is critical to operating the fuel cell. Further, the anode and cathode are formed using conductive material that are coated with various materials. At various points of construction and use of the fuel cell, the mechanical strength of the components are critical for assembly, conductivity, reactivity and operation. Sobolewski (col. 2, lines 45-65, col. 3, lines 45-55) discusses improved gas diffusion and improved mechanical characteristics in terms of improved flow resistance by using nanowires or nanorods.

Applicant further argues, “Another advantage identified by the Examiner, "improved electric conductivity" using nanowire or nanorods, is an incorrect statement against physical principles to a person of ordinary skill in the art. Electric conductivity of a conducting material (e.g., wire or rod) is inversely proportional to the sectional area of the material. Compared to normal scale rods or wires, nano rods or nano wires would have lower, rather than higher, electric conductivity.”

This argument is not persuasive. In an electrode for a fuel cell, surface area is critical to electric conductivity because the reactants are catalyzed across the surface and in the pores of the electode to give electrons and these electrons are required to flow from the anode to the cathode. The concept is different than simple electron flow because not all the electrons are formed in the same place. The surface area of the electrode must have the ability to conduct electrons across

the surface of the electrode. By using nanoparticles, Sobolewski teaches high electrical cross plane conductance (abstract). These features are clearly appreciated by the prior art.

Applicant further argues, "The cited references would not lead a person of ordinary skill in the art to have a reasonable expectation of success of the claimed invention. As discussed above, the advantages of a gas fuel cell disclosed in Sobolewski and Imazato using nano rods or nano wires are entirely irrelevant to an electrochemical cell as defined by the claimed invention. Therefore, a person of ordinary skill in the art would not have a reasonable of success to combine the teachings of Sobolewski and Imazato with those of Heller so as to arrive at the claimed invention."

This argument is not persuasive. One skilled in the art would recognize from the teachings of the art that the use of these materials in a fuel cell electrode would give the advantages noted in each references such as improved conductivity in the electrode, appropriate gas diffusion and increased mechanical strength. The various advantages taught in the references have been discussed in the previous section. Further, the fuel cells disclosed in Sobolewski and Imazato are argued to be not suitable for use within an implantable device. This argument is not persuasive. For example, hydrogen/oxygen implantable fuel cells are disclosed in patents US 3,837,922 and 6,503,648.

Examiner Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Ruthkosky whose telephone number is 571-272-1291. The examiner can normally be reached on FLEX schedule (generally, Monday-Thursday from 9:00-

6:30.) If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Ryan can be reached at 571-272-1292. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free.)

/Mark Ruthkosky/

Primary Examiner, Art Unit 1795